

# Social Sciences/Behavioral Parents/Legal Guardian Informed Consent

North Dakota Department of Human Services

## Information for Parents/Guardians of Children/Wards Who Take Part in Research Studies

The following information is being presented to help you decide whether or not you want to allow your child/ward to be a part of a minimal risk research study. Please read carefully. If you do not understand something, ask the Person in Charge of the Study.

**Title of Study:** \_\_\_\_\_

**Principal Investigator:** \_\_\_\_\_

**Study Location(s):** \_\_\_\_\_

Your child/ward is being asked to participate because... *(Indicate why the subject is being asked to participate. Try to keep the language clear & simple.)*

### General Information about the Research Study

The purpose of this research study is to...*(Explain completely)*

### Plan of Study

- *(Explain in detail what the subject will be required to do and how much time will be needed, weeks, days, hours, etc.)*

### Payment for Participation

- *(If the subjects are to be paid or compensated, specify the dollar amount and address the consequences of subject withdrawal or termination by the investigator; otherwise, simply state- You or your child will not be paid for your child's participation in this study.)*

### Benefits of Being a Part of this Research Study

- *(Explain what the benefits are, if any, to the subjects. For example, "You and/or your child/ward will experience...", or "By taking part in this research study, you may increase our overall knowledge of your..." ) Again, this explanation should be simple & clear.*

### Risks of Being a Part of this Research Study

- *(Explain what the risks are, even if they are minimal. Also, if there are no risks, so indicate.)*

### Confidentiality of Your Child's/Ward's Records

- Your child's/ward's research records will be kept *(Describe how)* to protect your child's/ward's privacy to the full extent of the law. However, authorized research investigators, the Department of Health and Human Services, the North Dakota Department of Human Services' Institutional Review Board, and other entities/individuals as required or authorized by law, may inspect your child's/ward's records from this research project.
- The results of this study may be published. However, the data obtained from your child/ward will be combined with data from other children/wards in the publication. The published results will not include your child's/ward's name or any other information that would personally identify your child/ward in any way.  
*[Be sure to explain whether code names or numbers will be used, who will have access to the data, and where will the data be kept.]*

### Volunteering to Be Part of this Research Study

- Your decision to allow your child/ward to participate in this research study is completely voluntary. You are free to allow your child/ward to participate in this research study or to withdraw him/her at any time. If you choose not to allow your child/ward to participate, there will be no penalty or loss of benefits you or your child are entitled to receive, if you remove your child/ward from the study. ***(You may wish to be explicit-e.g., removal from treatment, no grade penalty).***

### Questions and Contacts

- If you or your child/ward have any questions about this research study, contact ***(Identify person(s) and their telephone numbers.)***
- If you or your child/ward have questions about your child's/ward's rights as a person who is taking part in a research study, you or your child/ward may contact Dr. Christine Kuchler, Chair of the Department of Human Services' Institutional Review Board at 1-888-328-2662. ***[Required]***

### Your Consent—By signing this form I agree that:

- I have fully read or have had read and explained to me this informed consent form describing a research project.
- I have had the opportunity to question one of the persons in charge of this research and have received satisfactory answers.
- I understand that I am being asked to allow my child/ward to participate in research. I understand the risks and benefits, and I freely give my consent to allow my child/ward to participate in the research project outlined in this form, under the conditions indicated in it.
- I have been given a signed copy of this informed consent form, which is mine to keep.

_____ Signature of Parent/Guardian of Participant <b><i>[Required]</i></b>	_____ Printed Name of Parent/Guardian	_____ Date
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### Investigator Statement

I have carefully explained to the subject the nature of the above protocol. I hereby certify that to the best of my knowledge the subject signing this consent form understands the nature, demands, risks and benefits involved in participating in this study.

_____ Signature of Investigator Or Authorized research investigators designated by the Principal Investigator <b><i>[Required]</i></b>	_____ Printed Name of Investigator	_____ Date
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## Institutional Approval of Study and Informed Consent

This research project/study and informed consent form were reviewed and approved by the North Dakota Department of Human Services' Institutional Review Board for the protection of human subjects. This approval is valid until the date provided below. The board may be contacted at 1-888-328-2662.

**Consent Form Approval Date:**

**Approval Consent Form Expiration Date: (*Your proposed expiration date is subject to IRB review.*)**

- If this informed consent form has an "approval expiration date" that expires before the completion of this research study, the Principal Investigator may contact you for your re-consent at the time of expiration.

**[Please separate this page from the rest of the consent form. The informed consent should be read to the child/ward if necessary.]**

### Child's/Ward's Assent Statement

Dr./Mr./Ms. \_\_\_\_\_ Has explained to me the research study called: \_\_\_\_\_ **(Insert the title of your study).**

I agree to be in this study.

\_\_\_\_\_  
Signature of Child/Ward

\_\_\_\_\_  
Printed Name of Child/Ward

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Parent/Guardian

\_\_\_\_\_  
Printed Name of Parent/Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Printed Name of Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Printed Name of Witness

\_\_\_\_\_  
Date

OR

(Insert name of child/ward here) is unable to give assent for the following reason(s):

\_\_\_\_\_  
Signature of Parent/Guardian

\_\_\_\_\_  
Printed Name of Parent/Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Printed Name of Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Witness

\_\_\_\_\_  
Printed Name of Witness

\_\_\_\_\_  
Date

**Optional: (Please note: the statements below are optional, and may not apply to your study. Please delete them from this consent form if they do not apply.)**

***(This statement needs to be included if you are mailing the consent forms to the subjects and you will not be present when the subject signs this form.)***

**Investigator Statement:**

I certify that participants have been provided with an informed consent form that has been approved by the Department of Human Services' Institutional Review Board. That contains the nature, demands, risks and benefits involved in participating in this study. I further certify that a phone number has been provided in the event of additional questions.

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Printed Name of Investigator

\_\_\_\_\_  
Date

**In Case of Illness or Injury**

- Call *(list your name and phone number here)* in the event your child/ward gets sick or injured while participating in this study. If your child/ward has an emergency, go to the closest emergency room or clinic for treatment.
- After your child/ward has been treated for his/her illness or injury, call the Department of Human Services' Risk Manager at 701-328-2311, who will investigate the matter.

**If you are including Non-English speaking subjects in your study, a consent form in their language is required.**